

JUN 24 2004

OFFICIAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Graff et al.

Serial No. 10/627,451

Filed: July 25, 2003

For: *Colorectal Neoplasia*

Group Art Unit: 1623

Examiner: Khare, Devesh

Attorney Docket No. UTSD:0980

CERTIFICATE OF TRANSMISSION

I hereby certify that this corr is being transmitted by facsimile to the
Comm for Patents 703-872-9306 on June 24, 2004.

Signature

Richard Aron Osman

RESPONSECommissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner Khare:

Thank you for the Action dated Feb 25, 2004.

Restriction

Applicants confirm election of group II, and request reconsideration of the restriction. Group I consists of dependent claims 18-20 which recite a kit for delivering an aminoglycoside antibiotic having poor gut absorption, the kit comprising an aminoglycoside antibiotic having poor gut absorption, and an associated instructional medium describing use of the antibiotic in a claimed method. As such, these three claims depend for patentability on the corresponding method claims, and should require no additional search burden.

35USC112, second paragraph (specification): Claim 1-17

The claims require, inter alia, the step of (a) determining a patient is subject or predisposed to colorectal neoplasia. The claims and specification are directed to those skilled in the art; in particular those skilled at diagnosing and treating patients with colorectal neoplasia. Hence, those skilled in the art already know how to determine if a patient is subject or predisposed to colorectal neoplasia – that is their professional expertise. The claim is not

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delivery, which results in systemic distribution, primarily within the extracellular fluid. Specification, p.1, lines 17-22. For such systemic delivery, the high-pressure impulse transients of Hu may well provide for the desired localized enhanced drug delivery. However, our claims are restricted to *enteric* delivery into the gut of the target patient, and our claims specifically require an aminoglycoside antibiotic having poor gut absorption. The methods of Flotte do not appear to have any application to enterically restricted drugs.

Though we do not believe the cited art supports any prima facie case for obviousness, for good measure, we append an expert Declaration from Professor Graff, averring to the foregoing facts and conclusions. Accordingly, the uncontroverted evidence of record demonstrates that the cited art would not have suggested the claimed methods to one skilled in the art at the time the invention was made.

The Examiner is invited to call the undersigned if he would like to amend the claims to clarify the foregoing or seeks further clarification of the claim language.

We petition for and authorize charging our Deposit Account No.19-0750 all necessary extensions of time. The Commissioner is authorized to charge any fees or credit any overcharges relating to this communication to our Dep. Acct. No.19-0750 (order UTSD:0980).

Respectfully submitted,
SCIENCE & TECHNOLOGY LAW GROUP


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enc. Declaration under 37CFR 1.132 (5p).